Supplementary article data

A comparison of the diagnostic accuracy of MARS MRI and ultrasound of the painful metal-on-metal hip arthroplasty

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Appendix A – STARD checklist for reporting of studies of diagnostic accuracy

The 'Standards for the Reporting of Diagnostic accuracy studies' (STARD) checklist, version Jan. 2003, was used to improve the accuracy and completeness of this report and facilitate the assessment of bias (internal validity) and generalizability (external validity).

TITLE/ABSTRACT/KEYWORDS

1 *Identify the article as a study of diagnostic accuracy (recommend MeSH heading 'sensitivity and specificity').*
Title – A Comparison of the Diagnostic Accuracy of MARS MRI and Ultrasound of the Painful Metal-On-Metal Hip Arthroplasty

INTRODUCTION

2 *State the research questions or study aims, such as estimating diagnostic accuracy or comparing accuracy between tests or across participant groups.*
Aim – To determine the [diagnostic accuracy] sensitivity and predictive values of USS compared to MARS MRI [gold standard reference] for the detection of pseudotumors and muscle atrophy.

METHODS

Participants

3 *The study population: The inclusion and exclusion criteria, setting and locations where data were collected.*
Population:
– Patients with MOM hip replacements
Inclusion (MHRA Guidance – MDA/2012/036):
– Unilateral MOM hip patients with:
A large-diameter femoral head (≥36mm) as either a resurfacing or stemmed component; a symptomatic MOM hip (Oxford Hip Score ≤41/48)
– AND a MARS MRI scan within one year
Exclusion:
– Bilateral MOM hip patients
– Follow-up less than 12 months postoperatively
Setting:
– A tertiary orthopedic referral center
– Patients attending the specialist MOM outpatient clinic

4 *Participant recruitment: Was recruitment based on presenting symptoms, results from previous tests, or the fact that the participants had received the index tests or the reference standard?*
Recruitment based on 1) having retrospectively received the reference standard (MARS MRI) within the past year or 2) based on eligibility for new investigation (prospective MARS MRI and USS).

5 *Participant sampling: Was the study population a consecutive series of participants defined by the selection criteria in item 3 and 4? If not, specify how participants were further selected.*
Consecutive series of 19 patients.

6 *Data collection: Was data collection planned before the index test and reference standard were performed (prospective study) or after (retrospective study)?*
Data collection was planned prior to the index test [USS]. A prospective study design was used.

Test methods

7 *The reference standard and its rationale.*
At our center, MARS MRI is the current imaging gold-standard and has demonstrated good surgical correlation. Surgical validation is the ideal reference however this standard is not feasible for all patients as the majority is unlikely to undergo revision within the study time frame.

8 *Technical specifications of material and methods involved including how and when measurements were taken, and/or cite references for index tests and reference standard.*
See Methods; MARS MRI and USS protocol.

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9 *Definition of and rationale for the units, cut-offs and/or categories of the results of the index tests and the reference standard.*
See Appendix B; Classification of pseudotumors and muscle atrophy.

10 *The number, training and expertise of the persons executing and reading the index tests and the reference standard.*
Two consultant musculoskeletal radiologists in consensus agreement.

11 *Whether or not the readers of the index tests and reference standard were blind (masked) to the results of the other test and describe any other clinical information available to the readers.*
Radiologists blinded to the clinical details and were blind (masked) to the results of the other test.

Statistical methods

12 *Methods for calculating or comparing measures of diagnostic accuracy, and the statistical methods used to quantify uncertainty (e.g. 95% confidence intervals).*
Crosstab frequency tables used to calculate sensitivity, specificity, positive predictive value and negative predictive value.
95% confidence intervals calculated.

13 *Methods for calculating test reproducibility, if done.*
Test reproducibility not calculated. It was not appropriate to get one patient to have multiple scans.

RESULTS

Participants

14 *When study was performed, including beginning and end dates of recruitment.*
Over 6 months; recruitment from March – September 2012.

15 *Clinical and demographic characteristics of the study population (at least information on age, gender, spectrum of presenting symptoms).*
See Table 2; demographic and clinical data.
Population:
- Nineteen patients
- 15 females : 4 males
- Median age – 57 years
- 12 HRs : 7 THRs
- Mean OHS 25/48
- Median time since primary op: 61 months

16 *The number of participants satisfying the criteria for inclusion who did or did not undergo the index tests and/or the reference standard; describe why participants failed to undergo either test.*
- Eight patients identified with retrospective MARS MRI declined to participate due to difficulty in commute and time constraints.
- All potential patients identified from clinic agreed to take part in this study.

Test results

17 *Time-interval between the index tests and the reference standard, and any treatment administered in between.*
See Results. The mean time between MARS MRI and USS was 122 days (CI 69-156 days).

18 *Distribution of severity of disease (define criteria) in those with the target condition; other diagnoses in participants without the target condition.*
Pseudotumors: Disease was either present or absent.
Muscle Wasting: Disease was either present or absent.
In addition a grade one or more was classified as disease present.

19 *A cross tabulation of the results of the index tests (including indeterminate and missing results) by the results of the reference standard; for continuous results, the distribution of the test results by the results of the reference standard.*
See Appendix C.

20 *Any adverse events from performing the index tests or the reference standard.*
No adverse events reported.
Patients concerns and experience reported on a questionnaire. This includes claustrophobia for MARS MRI and pain (due to positions and transducer pressure) for the USS.

Estimates

21 *Estimates of diagnostic accuracy and measures of statistical uncertainty (e.g. 95% confidence intervals).*
See Table 3; Ultrasound diagnostic test characteristics.

22 *How indeterminate results, missing data and outliers of the index tests were handled.*
Indeterminate results were either excluded or assumed as a negative test; as this often implies failure of the imaging to detect pathology adequately.

23 *Estimates of variability of diagnostic accuracy between subgroups of participants, readers or centers, if done.*
Unpublished data (Nishii 2012 AAOS Abstract) report a PPV, NPV and accuracy of 84%, 78% and 85% respectively for the detection of pseudotumors using USS. The better diagnostic accuracy maybe attributed to only anterior scans used for analysis; our study includes anterior, lateral and posterior scans; the posterior scans may be more inaccurate.

24 *Estimates of test reproducibility, if done.*
Reproducibility not possible.

DISCUSSION

25 *Discuss the clinical applicability of the study findings.*
See discussion and conclusion.

Available online: http://www.stard-statement.org/ [date accessed on 22 May 2012].

Appendix B – Classification of pseudotumors and muscle atrophy using MARS MRI and ultrasound

The following grading system was used to classify pseudotumors and muscle atrophy on MARS MRI and ultrasound. MARS MRI pseudotumor classification (Hart et al. 2012) and MRI muscle atrophy classification (Bal and Lowe 2008).

Classification of pseudotumors and muscle atrophy using MARS MRI and ultrasound

	MARS MRI		Ultrasound	
Pseudotumors	Type I	Flat, thin-walled (≤2mm); fluid-like content	Type 1	Cystic lesion: internal fluid echo-texture; flat, thin-walled
	Type IIa	Thick-walled (>2mm); fluid-like content	Type 2	Cystic lesion: internal fluid echo-texture; atypical fluid; irregular thick-walled
	Type IIb	Thick-walled (>2mm); atypical fluid		
	Type III	Solid	Type 3	Solid lesion: complex solid echo-texture
Muscle atrophy	Grade 0	No change	Grade 0	No change
	Grade 1	Up to 30% reduction in muscle size	Grade 1	Less than 30% size reduction or with some fatty replacement
	Grade 2	30–70% fatty change and reduction in size	Grade 2	30–70% size reduction with fatty replacement
	Grade 3	> 70% fatty change with 80% reduction in size	Grade 3	> 70% size reduction with marked fatty replacement

Appendix C – Contingency frequency tables for statistical analysis

Note: the term 'disease' will be used to represent the pathology of interest being investigated in each case.

Contingency table. Gold standard test – MARS MRI

Ultrasound	Grade 0	Grade 1	Grade 2	Grade 3	Total
a) Gluteus medius muscle atrophy grading					
Grade 0	0	6	3	1	10
Grade 1	0	3	0	0	3
Grade 2	0	2	1	1	4
Grade 3	0	0	0	2	2
Total	0	11	4	4	19
b) Gluteus minimus atrophy grading					
Grade 0	1	3	4	2	10
Grade 1	0	1	1	0	2
Grade 2	0	2	0	1	3
Grade 3	0	1	1	2	4
Total	1	7	6	5	19
c) Iliopsoas muscle atrophy grading					
Grade 0	14	0	0	0	14
Grade 1	3	0	0	0	3
Grade 2	2	0	0	0	2
Grade 3	0	0	0	0	0
Total	19	0	0	0	19

Diagnostic screening frequency table. Gold standard test – MARS MRI

USS test result	Disease	No disease	Total
a) Pseudotumors			
Positive	9	1	10
Negative	4	5	9
Total	13	6	19
b) Gluteus medius muscle atrophy			
Positive	9	0	9
Negative	10	0	10
Total	19	0	19
c) Gluteus minimus muscle atrophy			
Positive	9	0	9
Negative	9	1	10
Total	18	1	19
d) Iliopsoas muscle atrophy			
Positive	0	5	5
Negative	0	14	14
Total	0	19	19
e) Gluteus medius tendon abnormality			
Positive	5	5	10
Negative	3	6	9
Total	8	11	19
f) Gluteus minimus tendon abnormality			
Positive	4	4	8
Negative	3	8	11
Total	7	12	19
g) Iliopsoas tendon abnormality			
Positive	1	6	7
Negative	0	12	12
Total	1	18	19

Appendix D – Summary of pseudotumors identified using MARS MRI and ultrasound for each patient

Summary of pseudotumors identified using MARS MRI and ultrasound for each patient

Patient number	Pseudotumors (location as seen on) MARS MRI	Ultrasound (USS)	Agreement
1	None	None	Yes
2	Anterior Lateral	None Lateral	Yes
3	Anterior None	None Lateral	Yes
4	Anterior	Anterior	Yes
5	None	None	Yes
6	Anterior Posterior	Anterior None	Yes
7	Anterior Lateral None	Anterior Lateral Posterior	Yes
8	Anterior	Anterior	Yes
9	Anterior	Anterior	Yes
10	None None	Anterior Posterior	No: MARS MRI missed anterior lesion
11	None	None	Yes
12	Lateral	None	No: USS missed lateral lesion
13	None	None	Yes
14	Posterior	Posterior	Yes
15	Lateral	None	No: USS missed lateral lesion
16	Anterior	None	No: USS missed anterior lesion
17	Lateral	None	No: USS missed lateral lesion
18	None	None	Yes
19	Anterior	Anterior	Yes